

## **37 CFR § 1.132 Declaration of Diana J. Parsons**

### **BACKGROUND**

1. My name is Diana Jean Parsons. I am over 18 years of age. I currently reside in Sausalito, California and work in Berkeley and San Francisco, California. I have personal knowledge of the facts set forth in this declaration.
2. I received my Bachelor of Arts degree from Stanford University in June 1970.
3. In 1970-71 I was a volunteer English teacher in the Japanese Peace Corps in Tokyo (as a participant in the Volunteers in Asia program at Stanford University).
4. In 1971 I returned to Stanford University as a graduate-at-large to finish the science prerequisites for medical school.
5. I received my MD degree from Stanford University Medical School in June 1976.
6. I completed my internship in General Surgery at Stanford University Hospital in June 1977 and am licensed to practice medicine in California.
7. I completed my residency in Plastic & Reconstructive Surgery at the Stanford University Hospitals in June 1982.
8. I started my own solo private practice of Plastic & Reconstructive Surgery in Berkeley, California in July 1982.
9. I received "Patent Pending" status for my U.S. Patent Application No. 10/735,362 in December 2002. Since that time I have specialized in that skin rejuvenation process in both Berkeley and San Francisco, California.

### **DISCUSSION**

10. I have reviewed the Patent Office Action dated April 1, 2008, including the Patent Examiner's reasons for rejecting the pending claims based on the ruling that the specification is not enabling to one of ordinary skill in the art and that the claims are obvious over Goldberg et al (Skin resurfacing utilizing a low-fluence Nd:YAG laser, J Cutan Laser Ther. 1999:23-27) in view of Alster (Combined Laser Resurfacing and Tretinoin Treatment of Facial Rhytides, Cosmetic Dermatology, Volume 10, No. 11, November 1997) in view of Ho et al (Dermatologic Surgery, 1995 December, 21 (12), 1035-7) and Kye YC (Dermatologic Surgery, 1997 October 23 (10): 880-883), and provide the following comments.
11. My method for producing sustained skin rejuvenation using a Q-Switched Nd:YAG laser stems from the method developed by Tankovich et al (U.S. Patent Nos. 5,423,803 and 6,036,684). The laser parameters are as follows: pulse duration of about 0.001 to 1.0 microseconds, wave length of about 800nm to 1200nm, fluence of about 1 to 3 J/cm<sup>2</sup>, and pulse

frequency of 1 to 20 per second. This laser has no inherent target in the skin. A skin contaminant consisting of a mixture of 20% by weight of one micron graphite particles in mineral oil is painted on the skin. The laser light causes the carbon particles to explode. Persons of ordinary skill in the art produce whatever degree of carbon explosion desired by simply varying the rate at which the light is passed over the skin. For example, moving the light very quickly does not explode any particles; the skin remains covered by the black solution. If the light is passed very slowly, some of the surface cells are damaged and can result in redness and pain. It is well-known to persons of ordinary skill in the art that the rate at which the light is passed can be adjusted to explode the carbon particles without removing any epidermis (a non-ablative process).

12. A person of ordinary skill in the art would know that exploding carbon particles on the skin without removing any epidermis would not produce any effective treatment of the skin because it is widely believed that some removal of skin, at least sufficient to cause erythema, is necessary to get a cosmetic effect.

13. A person of ordinary skill in the art would know when the carbon particles have exploded because they disappear as they explode, so that the skin that was under the particles becomes visible, even though no epidermis has been removed and the epidermis remains intact.

14. I describe in the specification that "the laser beam is scanned over the area treated with the activating solution so as to clean substantially all of the mixture from the skin surface by exploding or fracturing the carbon or graphite particles in the oil. This scanning process takes from about 2 to 10 minutes to complete on the face, usually about 4 minutes" (page 9, lines 7-10). This information provides sufficient directions to one of ordinary skill in the art as to know how quickly to move the laser light over the carbon particles on the skin. The sentence on page 7, lines 10-12 of the specification contains the phrase, "As the particles explode, they cause removal of the stratum corneum" was written in error. Instead of "stratum corneum" the words should have been "carbon particles," which would have been consistent with the description on page 9 lines 7-10. I am thankful that the Examiner caught this inconsistency. This error would have been obvious to one of ordinary skill in the art because it was inconsistent with the rest of the specification (a non-ablative process). One of ordinary skill in the art would know that removing the stratum corneum does not leave the epidermis intact, and the method clearly requires leaving the epidermis intact. Removal of the sentence on page 7, lines 10-12, makes the specification consistent.

15. The Examiner maintains that the phrase in step 43 of figure 3: "...and reveals the underlying skin" means that the skin has been removed. One of ordinary skill in the art would reasonably understand this phrase to mean: reveal the skin that was underneath the carbon particles which were removed by the laser induced explosion. This meaning is consistent with the description on page 9, lines 7-10 of the specification which describes cleaning "substantially all of the mixture from the skin surface by exploding or fracturing the carbon or graphite particles in the oil. There simply is no language in step 43 of figure 3 about removing skin and there is no basis for such an interpretation.

16. The references of Alster, Ho, and Kye are not related to my method of producing a sustained rejuvenation of the skin because none of these references disclose or describe a method of exploding carbon particles on the skin, wherein there is no removal of the epidermis, such that the method, by itself, is ineffective in treating the skin. The methods in all these references cause

the removal of skin. This removal of skin prevents these methods from being useful continuously over a period of several years because they will eventually damage the skin permanently. This fact is well known to those of ordinary skill in the art.

17. The references of Alster, Ho, and Kye would not suggest to one of ordinary skill in the art to use a method of exploding carbon particles on the skin, which is ineffective in treating the skin by itself, in combination with intermittent use of retinoic acid, because one of ordinary skill in the art would have no reasonable expectation that such a combination would be effective in improving the appearance of the skin. There is nothing in the field of cosmetic surgery that would suggest such a result. In fact such a result would be unexpected. One of ordinary skill in the art would not expect the combination of intermittent application of retinoic acid plus exploding carbon particles which do not remove skin to produce any beneficial effect on the skin. This is because there is no basis in the art that would predict a beneficial result. Furthermore, one of ordinary skill in the art would not expect intermittent use of retinoic acid to produce sustained skin rejuvenation effect by itself.

18. The method of Goldberg is identical to the method of Tankovich. Quoting from U.S. Patent No. 6,036,684, page 4 line 64 "Preliminary Biopsy Studies": "...Our preliminary conclusions from these studies indicate new collagen fiber formation in the upper part of the dermis immediately below the epidermal basal membrane...There appears to be an increase in the portion of young collagen fibers...We also observe...an increase in plasmocytes and young fibroblasts. These preliminary observations indicate a positive effect of the treatment in the upper layers of the dermis tissue. We have not yet developed an explanation for this indicated effect..." The method was three treatments given 4 weeks apart, using multiple passes of the laser light to both drive the activating solution deeper into the skin and down the hair shafts to deliver heat deeper into the dermis. The study was terminated after 8 months. There was no unifying theory to seek or expect sustained skin rejuvenation. The Goldberg study showed modest improvement in superficial skin lines. When I used this method it was cumbersome, slow, and, to many patients painful. By speeding up the rate of exploding the carbon particles on the skin, as one with ordinary skill in the art would know how to do, the patients were more comfortable, there was no erythema, the epidermis remained intact, but there was no significant effect on the skin. Based on the biopsy studies quoted above, I speculated that there was insufficient new collagen production just below the basement membrane because the focus of the Tankovich/Goldberg method was to produce more heat in the deeper dermis. Based on the science of wound healing, I further speculated that if I could produce chronic deposition of new collagen and sustain chronic remodeling of the collagen as it matured several months later located just under the basement membrane, one might see a sustained improvement in the appearance of the epidermis as a non-ablative procedure. By using low fluence and leaving the epidermis intact I believed I could repeat the treatments as often as desired and year after year to give the appearance of rejuvenated skin. I experimented with various modifications of the exploding particle method leaving the epidermis intact. I was reluctant to use topical retinoic acid because retinoic acid causes skin redness and sensitivity to the sun. Repeated use can cause loss of pigment, painful irritation, dryness, swelling of the skin, and contact dermatitis (see specification page 2, lines 4-5). I considered the possibility of using a minimal exposure of the skin to retinoic acid which would not produce these side effects. However, such minimal exposure to retinoic acid by itself is not effective in producing a sustained improvement in the appearance of the skin. I was not optimistic that such minimal exposure to retinoic acid would be beneficial in combination with an exploding particle method which, by itself did not remove skin. I eventually developed a protocol of intermittent (8-16 treatments per month) retinoic acid application (using a

concentration of less than 1%). This combination of exploding carbon particle treatment plus intermittent retinoic acid treatment, resulted in an unexpected remarkable improvement in the appearance and condition of the skin (see specification, pages 7 and 8). I have been using this method of skin rejuvenation since 2003 with great success.

19. For the foregoing reasons, the specification is enabling to one of ordinary skill in the art and the claims as amended are not obvious over Goldberg, in view of Alster, Ho, and Kye.

20. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of any patents issuing from the instant patent application.

Executed on August 26, 2008.

  
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Diana J. Parsons